

REMARKS

Favorable reconsideration is respectfully requested in view of foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-9 are pending in this application.

Claims 2, 5, 7 and 8 are withdrawn as non-elective subject matter.

Claims 1, 3, 4, 6 and 9 have been examined on the merits that stand rejected.

Claims 1-9 have been amended to make minor editorial revisions to better conform to U.S. claim form and practice. Such revisions are non-substantive and not intended to narrow the scope of protection. The revisions include: revising the beginning in the claims to recite "A" or "The" where needed, revising the claim language throughout to provide proper antecedent basis to the claims; revising the claim language to use more conventional claim terminology to conform to U.S. claim form and practice. Support can be found in original claims 1-9.

It is noted that claim 9 has been rewritten as a proper method claim, including positive method steps. It is based on claim 9 as filed. Further support can be found at page 4, lines 5-8, and at page 5, lines 1-29.

No new matter has been added by the above claim amendments.

Applicant notes the amended claims do not present any new issues for consideration in/or search as they simply incorporate subject matter already considered by the Office in the previous claims. Accordingly, if the next Office Action on the merits includes a new ground of rejection of one or more claims, the Action should be non-final.

Applicant is submitting the present amendment without prejudice to the subsequent prosecution of claims to some or all of the subject matter which might be disclaimed by virtue of this response (although none is believed to be), and explicitly reserves the right to pursue some or all of such subject matter, in divisional or continuation applications.

Applicant thanks the Examiner for the careful examination of this case and respectfully requests reexamination and reconsideration in the case, as amended. Below Applicant addresses the rejections in the office action and explains why the rejections are not applicable to the pending claims as amended.

II. CLAIM OBJECTIONS

Claims 1, 3-4 and 6 were objected to for containing the minor informalities noted at the bottom of page 2 of the Office Action.

The present amendment overcomes this objection by amending the claims to correct the noted informalities to better

conform to U.S. claim form and practice. Therefore, withdrawal of the rejection is requested.

III. PATENTABLE SUBJECT MATTER REJECTION

Claim 9 was rejected under 35 U.S.C. § 101 on the basis that it is an improper method claim for failing to recite proper method steps for the reasons noted at the top of page 3 of the Office Action.

The present amendment overcomes this rejection by rewriting the claim to a proper method claim, including active method steps. Therefore, withdrawal of the rejected is requested.

IV. INDEFINITENESS REJECTIONS

Claims 1, 3-4, 6 and 9 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons set forth on pages 3-4 of the office action.

This rejection is respectfully traversed.

Applicants have amended the claims to better define the subject matter more clearly and distinctively in a non-narrowing manner. It is believed that the amended claims conform to claims conform to U.S. practice for reasons which are self-evident.

The claims are thus clear, definite and have full antecedent basis. This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

V. PRIOR ART REJECTIONS

Claims 1, 4, 6 and 9 were rejected under 35 U.S.C. § 103(a) as being obvious over BOMBARDELLI et al. (EP 0693278) and NISHIZAWA (JP 09157136) for the reasons on pages 5-7 of the Office Action.

Claims 1, 3-4, 6 and 9 were rejected under 35 U.S.C. § 103(a) as being obvious over DI PIERRO (WO 02/098436 A) and DWEEK (1999) in view of BOMBARDELLI (U.S. 5,376,371) for the reasons on pages 7-9 of the Office Action.

These rejections are respectfully traversed and will be discussed together below.

Applicant respectfully submits that the combined cited references fail to disclose or suggest each and every element of the claims as amended, and in fact teach away from the claimed subject matter. Applicant further submits that the claimed invention achieves surprising and unexpected results indicative of non-obviousness.

Based on the Office's analysis, it is clear that cited references actually teach away from the invention of claims 1-9. In this regard, claims 1-9 are directed to topical composition for the treatment of sexual dysfunction. In this regard, the references relate to compositions to promote hair growth. Nothing in the cited references discloses anything about using the combined elements in the claimed composition to treat sexual dysfunction.

The claimed combination of ingredients is able to increase sexual performances, especially in women, as can be seen in the test carried out on female volunteers (see page 5, last paragraph to page 6 of the PCT application, published WO2005/004890 to which the instant application is a National stage application).

On the contrary, the cited prior art references teach how to treat hair loss or stimulate hair growth (BOMBARDELLI, EP693278 and NISHIZAWA), or alternatively how to treat adiposities and cellulite (DI PIERRO), increase capillary resistance and reduce oedema (DWEEK) and treat fat deposits (BOMBARDELL US 5376371). There is no suggestion that combining the presently claimed active ingredients in a pharmaceutical composition would result in a novel, effective therapeutic approach to treat sexual dysfunction. The skilled person faced with the problem of finding a new composition for treating sexual dysfunction would not look at the cited references which, as seen, deal with a completely different technical problems.

In addition, it is submitted that the active ingredients making up the claimed composition were unexpectedly found to behave synergistically, as can be seen in the experiments carried out by the Applicant and discussed below.

For comparative purposes, 20 women aged from 35 to 45 having normal sexual activity were topically treated with 0.2 ml of a gel formulation, as follows:

Group 1: control (placebo)
Group 2: gel containing 1% esculoside
Group 3: gel containing 2% ethyl ximenynate
Group 4: gel containing 0.2% purified extract of
coleus > 80%
Group 5: gel according to example 1 of the present
application.

The hemodynamic of vulvar mucosa was examined by means of laser-doppler flowmeter at time 0 and after 30 and 60 min from the topical application of the formulation (Sarrel Ph. M. and Brinda W, *Fertility and Sterility*, 68, 6, 1997).

The results are reported in the following Table:

| Treatment | Flow in the vulvar mucosa (mV) (M±S.E.) | | |
|-----------|---|----------|----------|
| | Basal | 30min | 60min |
| Group 1 | 231±25 | 228±31 | 241±30 |
| Group 2 | 241±33 | 244±29 | 263±30 |
| Group 3 | 235±28 | 253±30 | 271±43 |
| Group 4 | 239±26 | 244±33 | 289±36 |
| Group 5 | 250±31 | 375±29** | 473±41** |

**p<0.001 Split-plot Anova

These results indicate that the composition according to the present application strongly increases the hematic flow in the vulvar mucosa 30 min after topical application and reaches the maximum effect at 60 min.

On the contrary, each single component (by itself) only caused a slight increase of the hematic flow at each time point and the sum of the individual effects is significantly lower than the increase observed in Group 5 (according to the invention).

Based on the evidence herein submitted, it can be concluded that the combined ingredients of the composition, according to claims 1-9, behave synergistically to achieve a surprising and unexpected property over the compounds in the combined prior art teachings.

On pages 6 and 8 of the Office Action, the Examiner argues that the "intended use" of the claim compositions does not distinguish the composition over the prior art compositions containing the individual ingredients, as such intended use would be inherent in the compositions of the cited prior art teachings.

In reply, it is believed that the combined ingredients in the composition of the claims achieve surprising and unexpected properties over the compositions of single ingredients in the cited prior art references for the reasons noted above. It is well-established that a compound and all of its properties are inseparable and thus an unexpected property can lead to a use that was not just new but also unexpected. See In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007) and In re Papesch, 315 F.2d 381 (CCPA 1963).

In other words, the unexpected and surprising synergistic properties of the claimed composition should be

considered with respect to the new and unexpected use of the claimed composition. This is true for both the compositions and the amended method claim. It is believed that the combined elements of the claimed composition achieves surprising and unexpected results that are indicative of the non-obviousness of the claims over the cited prior art references. It is well established that the presence of surprising and unexpected properties are evidence of non-obviousness. M.P.E.P., Eighth Edition, Revision 6 (September 2007) at § 716.02 (a) I-IV and § 2145.

In view of such, it is believed that the present invention is non-obvious over the combined teachings of the cited prior art references. Therefore, amended claim 1 and all the claims depended thereon, including revised method claim 9, are believed to be novel and patentable over the cited prior art references.

Therefore, withdrawal of the above 103(a) obviousness rejections is respectfully requested.

VII. CONCLUSION

In view of the foregoing amendments or remarks, it is respectively submitted that the present application is in condition for allowance and our only notice of that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Jay F. Williams, Reg. No. 48,036
Customer No. 00466
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

JFW/jr